

**California Health and Human Services Agency  
Committee for the Protection of Human Subjects**

**New Project Application and Review Checklist**

Date: \_\_\_\_\_

Project Title: \_\_\_\_\_

Institutional Affiliation: \_\_\_\_\_

Principal Investigator (PI): \_\_\_\_\_

Mailing Address: \_\_\_\_\_

Telephone: \_\_\_\_\_ Fax: \_\_\_\_\_ E-mail: \_\_\_\_\_

Have you included the following (please check)?

All Projects:

- ☐ Cover Letter
- ☐ New Project Application and Review Checklist
- ☐ Project Protocol
- ☐ Signature of P.I.(s) on New Project Application and Review Checklist
- ☐ Signatures of P.I. and Responsible Official on Project Protocol
- ☐ C.V. of Principal Investigator(s)

Other Possible Items (check if submitted in research proposal):

- ☐ Checklist for Research Involving Children
- ☐ Checklist for Research Involving Pregnant Women and Fetuses
- ☐ Checklist for Research Involving Neonates
- ☐ Checklist for Research Involving Prisoners
- ☐ Informed Consent Form
- ☐ Letters of administrative approval
- ☐ Grant application
- ☐ C.V. of translator
- ☐ Additional project materials

Specify: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

Type of Review Requested (check one):

- ☐ Full committee review
- ☐ Expedited review (available only for projects without any direct human contact, such as projects using pre-existing data or specimens)

**THIS SHADED AREA IS  
FOR CPHS STAFF USE  
ONLY**

**Project Number:**

**Reviewer:**

**Date to Reviewer:**

**Staff Reviewer:**

- |                              |                             |
|------------------------------|-----------------------------|
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |

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|------------------------------|-----------------------------|
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |
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| <input type="checkbox"/> Yes | <input type="checkbox"/> No |

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|------------------------------|-----------------------------|
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Reviewer  
Concurs:

1. Is there adequate documentation in the protocol that the selection of subjects is equitable? ☐ Yes ☐ No ☐ Yes ☐ No
2. Are adequate justifications provided in the protocol for both the quantity of the data and the variables being requested? ☐ Yes ☐ No ☐ Yes ☐ No
3. Is the data set to be linked with any other data sets? ☐ Yes ☐ No ☐ Yes ☐ No  
**If yes**, are all data sets identified and each of the variables listed and justified for each linkage? ☐ Yes ☐ No ☐ Yes ☐ No
4. Will any of the following categories of vulnerable subjects be involved (please check)? Please note that if the project involves contact with these subjects (not just use of data) the appropriate checklist should be submitted with this application:  
Pregnant women or fetuses ☐ Neonates ☐ Prisoners ☐ Children ☐ ☐ Yes ☐ No
5. Is there adequate documentation in the protocol that research design is scientifically sound? ☐ Yes ☐ No ☐ Yes ☐ No
6. Is there adequate documentation in the protocol that the risk to subjects is reasonable in relation to the anticipated benefits to the subjects/society? ☐ Yes ☐ No ☐ Yes ☐ No
7. The risk level of this research is: Minimal ☐ Moderate ☐ High ☐ ☐ Yes ☐ No
8. The risks of this research are (check all that apply):  
Physical ☐ ☐ Yes ☐ No  
Psychological ☐ ☐ Yes ☐ No  
Social ☐ ☐ Yes ☐ No  
Economic ☐ ☐ Yes ☐ No  
Data security and confidentiality ☐ ☐ Yes ☐ No
9. Will a third party be used to perform the data matching? ☐ Yes ☐ No ☐ Yes ☐ No  
**If yes**, has evidence been provided of the third parties' ability to protect confidential, sensitive information? ☐ Yes ☐ No ☐ Yes ☐ No
10. Is an adequate plan provided in the protocol to protect the data from improper use, including the implementation of effective security measures such as:  
Locked cabinets or rooms? ☐ Yes ☐ No ☐ Yes ☐ No  
Computer password protected? ☐ Yes ☐ No ☐ Yes ☐ No  
Limiting access to those with a need to know? ☐ Yes ☐ No ☐ Yes ☐ No  
Other? \_\_\_\_\_
11. Has a commitment been made in the protocol that the data will not be reused or provided to any other person or entity? ☐ Yes ☐ No ☐ Yes ☐ No

Project Number:

**Reviewer  
Concurs:**

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|-----|--|--|--|
| 12. | Has a commitment been stated in the protocol to not publish information that could possibly lead to identification of individual subjects?             | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 13. | Has an adequate plan been provided in the protocol to destroy or return the data as soon as it is no longer needed for research?                       | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 14. | Will the research involve small cells?   | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
|     | <b>If yes</b> , have appropriate and sufficient methods to protect the identity of individual subjects been described in the protocol?                 | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 15. | Is a waiver of patient authorization being requested for HIPAA compliance?   | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
|     | <b>If yes</b> , has the following information been provided:   |  |  |
|     | • A detailed description of the protected health information, including name of HIPAA covered entity(ies), name(s) of database(s), and variables?      | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
|     | • Adequate evidence that the research could not be practicably conducted without access and use of protected health information?                       | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
|     | • Data protection measures (items 10-14 above) have been adequately described in the protocol?   | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 16. | Is informed consent required?  | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
|     | <b>If yes</b> , does the <b>informed consent form</b> provide:   |  |  |
|     | • A description of the study (statement that the study involves research and explanation of the purpose, subject selection, duration, and procedures)? | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
|     | • A description of risks or discomfort?  | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
|     | • A description of measures to protect confidentiality of subjects and records?  | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
|     | • A description of benefits to subjects/others?  | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
|     | • A disclosure of alternative procedures or treatments?  | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
|     | • A statement of compensation or treatment for injury?   | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
|     | • A statement of any potential conflicts of interest that may affect research results?   | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
|     | • A statement of funding source of project?  | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
|     | • A statement of whom to contact with questions about the research?  | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
|     | • A statement of whom to contact about the rights of research subjects?  | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
|     | • A statement of whom to contact regarding research-related injury?  | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
|     | • A statement of voluntary participation and the right to discontinue without penalty?   | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |

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|---|--|--|
|   |  | <b>Project Number:</b><br><b>Reviewer</b><br><b>Concurs:</b>   |
| 17. Is a waiver of informed consent being requested?<br><b><i>If yes, is there documentation in the protocol that:</i></b>  | <input type="checkbox"/> Yes <input type="checkbox"/> No   | <input type="checkbox"/> Yes <input type="checkbox"/> No   |
| • The risk to subjects is minimal?  | <input type="checkbox"/> Yes <input type="checkbox"/> No   | <input type="checkbox"/> Yes <input type="checkbox"/> No   |
| • The rights and welfare of subjects will not be adversely affected?  | <input type="checkbox"/> Yes <input type="checkbox"/> No   | <input type="checkbox"/> Yes <input type="checkbox"/> No   |
| • The research could not be practically carried out without a waiver?   | <input type="checkbox"/> Yes <input type="checkbox"/> No   | <input type="checkbox"/> Yes <input type="checkbox"/> No   |
| • When appropriate, the subjects will be provided with additional information later?  | <input type="checkbox"/> Yes <input type="checkbox"/> No   | <input type="checkbox"/> Yes <input type="checkbox"/> No   |
| 18. Are there potential conflicts of interest that could affect the quality of the research?<br><b><i>If yes</i></b> , please specify:                                      | <input type="checkbox"/> Yes <input type="checkbox"/> No   | <input type="checkbox"/> Yes <input type="checkbox"/> No   |
| 19. Is the project budget sufficient?   | <input type="checkbox"/> Yes <input type="checkbox"/> No   | <input type="checkbox"/> Yes <input type="checkbox"/> No   |
| 20. Indicate the amount of funding project receives from each source listed below.<br>Federal \$ _____ State \$ _____ Foundation \$ _____ Other \$ _____<br>Total: \$ _____ |  | <input type="checkbox"/> Yes <input type="checkbox"/> No   |
| 21. Will an investigational drug(s) be used?<br><b><i>If yes</i></b> , is there an IND application?   | <input type="checkbox"/> Yes <input type="checkbox"/> No<br><input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No<br><input type="checkbox"/> Yes <input type="checkbox"/> No |
| 22. Will an investigational device be used?<br><b><i>If yes</i></b> , has it received FDA premarket approval, approval, or exemption?                                       | <input type="checkbox"/> Yes <input type="checkbox"/> No<br><input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No<br><input type="checkbox"/> Yes <input type="checkbox"/> No |
| 23. If an investigational drug or device will be used, have the procedures for adequately monitoring the safety of the subjects been described in the protocol ?            | <input type="checkbox"/> Yes <input type="checkbox"/> No   | <input type="checkbox"/> Yes <input type="checkbox"/> No   |
| 24. Will translated documents be used?<br><b><i>If yes</i></b> ,  | <input type="checkbox"/> Yes <input type="checkbox"/> No   | <input type="checkbox"/> Yes <input type="checkbox"/> No   |
| • Specify language(s): _____  |  |  |
| • Has adequate evidence of the translator's ability been provided?  | <input type="checkbox"/> Yes <input type="checkbox"/> No   | <input type="checkbox"/> Yes <input type="checkbox"/> No   |

25. List the formal names of State databases to be used in this project.

Department	Name of Database(s)
Dept. of Health Services	
Office of Statewide Health Planning and Development	
Dept. of Mental Health	
Dept. of Developmental Services	
Dept. of Social Services	

Other (Specify)	
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26. Check the box which indicates the nature of each CA. Health and Human Services Agency department's involvement – e.g., funding, principal investigator (PI), research staff, or supplying human subjects (note that only subjects for which the State has direct responsibility, e.g., mental hospital patients should be included.)

Dept.	Funding	PI	Staff	Subjects
DHS				
OSHPD				
DMH				
DDS				
DSS				
Other				

Principal Investigator Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**CPHS Expedited Review Use Only**

- |  |  |
|--|--|
| <input type="checkbox"/> Approved for Common Rule  | <input type="checkbox"/> Common Rule approval deferred pending minor revisions |
| <input type="checkbox"/> Approved for HIPAA waiver | <input type="checkbox"/> HIPAA waiver deferred pending revisions               |
| <input type="checkbox"/> Refer to full committee   |  |

Comments and additional information:

Reasons for Deferral or Referral to Full Committee:

Reviewer Signature: \_\_\_\_\_ Date: \_\_\_\_\_